10 CFR PART 21
DRAFT REGULATORY BASIS
REVISION 1

April 28, 2015

Part 21 Rulemaking Public Meeting

Meeting Ground Rules

- Category 3 (provide public with opportunity to comment)
- Short presentations followed by question
- Open discussion session from 4:15pm – 5:00pm
- Please limit questions to topic at hand
- Silence electronic devices
- No food or beverages in hearing room
- Security escort available to move about the floor
- Phone line instructions
- Meeting transcribed
- Breaks / Restrooms
- Feedback forms
- Emergency exits

Part 21 Rulemaking Public Meeting

- **Purpose of the Meeting**
  - Discuss the content of Revision 1 of the draft regulatory basis to clarify 10 CFR Part 21, “Reporting of Defects and Noncompliance” (Part 21)
  - Present the areas of Part 21 in which the NRC staff is proposing rulemaking

Meeting Agenda (Morning)

Time	Topic	Led by
9:00am - 9:10am	Opening Remarks and Logistics	Facilitator
9:10am - 9:30am	Part 21 History and Need for Rulemaking	Heath, J
9:30am - 10:15am	Evaluating and Reporting, Sections 4, 5, & 6	Heath, J
10:15am - 10:30am	Break	
10:30am - 11:00am	Evaluating and Reporting, Sections 9 &11	Huckabay, V
11:00pm - 11:30pm	Commercial Grade Dedication, Sections B, C, & D	Prescott, P
11:30pm - 12:00pm	Commercial Grade Dedication, Sections E, F, & G	Huckabay, V
12:00pm - 1:00pm	Lunch	

Meeting Agenda (Afternoon)

Time	Topic	Led by
1:00pm - 2:30pm	Evaluating and Reporting, [Fuel Cycle Facilities]	Atack, S
2:30pm - 2:45pm	Break	
2:45pm - 4:00pm	Commercial Grade Dedication, [Fuel Cycle Facilities]	Atack, S
4:00pm – 4:15pm	Administrative Changes	Huckabay, V
4:15pm - 5:00pm	Open Discussion	Facilitator
5:00pm	Meeting Adjourn	

Part 21 Working Group

- **Working Group Members:**
  - **NRO/DCIP** - Jermaine Heath, Victoria Huckabay, Paul Prescott
  - **NRO/DARR** – Yanely Malave
  - **NMSS/FCSS** - Sabrina Atack, Jonathan DeJesus
  - **OGC** – Geary Mizuno
- **Responsibility of the working group:**
  - Identify Part 21 areas of improvement
  - Develop the regulatory (technical) basis

Part 21 Working Group

- **Working Group Members:**
  - **NRO/DCIP** - Jermaine Heath, Victoria Huckabay, Paul Prescott
  - **NRO/DARR** – Yanely Malave
  - **NMSS/FCSS** - Sabrina Atack, Jonathan DeJesus
  - **OGC** – Geary Mizuno
- **Responsibility of the working group:**
  - Identify Part 21 areas of improvement
  - Develop the regulatory (technical) basis

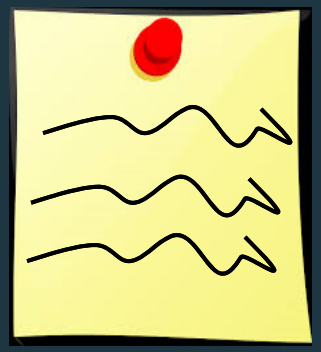
Rulemaking Timeline

YOU ARE STILL HERE

Identify need for rulemaking	Regulatory (Technical) Basis	Proposed Rule	Final Rule
NRC staff issued user need memo in 2009	• Foundation of effective rulemaking • Public meetings • Draft rule text	• Draft text & guidance • 75 day public comment period (typically)	•Final text & guidance •Implementation period (if needed) •Public meetings on implementation

Opportunities for public participation

Timeline - Historical



- **2009:** User Need memo
- **2010:** OIG audits identified issues with Part 21
- **2011:** Informed Commission of plan to develop regulatory basis to clarify Part 21 (SECY-11-0135)
- **2012:** Issued Rev 0 of Draft Regulatory Basis

Timeline – Moving Forward

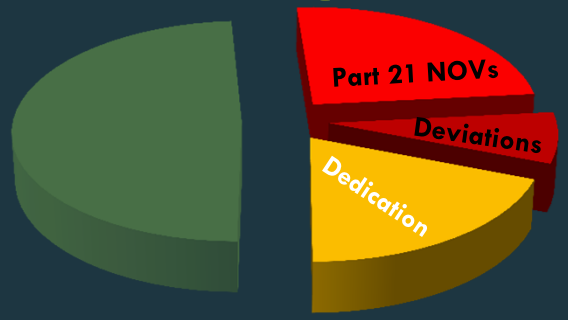
Event	Date
Release Revision 1 of the Draft Regulatory Basis	March 2015
Public Meeting to Discuss Draft Regulatory Basis Rev. 1	April 2015
Issue Final Regulatory Basis	June 2015
Publish Proposed Rule and Draft Regulatory Guides	2016
Publish Final Rule	2018

Purpose of Part 21 Rulemaking

- **Clarify the requirements of Part 21**
  - Proposed changes to the regulations
  - Guidance development
    - NRC Regulatory Guides
    - Industry Guidance (EPRI, NEI)
- **Areas of clarification**
  - Evaluating and reporting
  - Commercial grade dedication

Part 21 Rulemaking – What is it?

- NRC staff's proposal to clarify 10 CFR Part 21 as prescribed in SECY-11-0135
  - Simplify rule language when possible
  - Provide updated Regulatory Guidance
- Developed 25 Areas for Improvement in 3 categories:
  - Evaluating & Reporting
  - Commercial Grade Dedication
  - Administrative Changes



- Use stakeholder input to improve the Part 21 process
  - Additional areas for improvement identified at public meetings

Regulatory Guidance

- **Regulatory Guidance development is integral to rulemaking process**
  - DG-1291, Evaluating Deviations and Reporting Defects and Noncompliance
  - DG-1292, Dedication of Commercial Grade Items
  - DG-1305, “Design and Analysis Computer program Commercial-Grade Dedication Requirements”

Regulatory Guidance

Regulatory Guidance development underway…

- DG-1291, "Evaluating Deviations and Reporting Defects and Noncompliance" could address:
  - NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance."

Regulatory Guidance

Regulatory Guidance development underway…

- DG-1292, Dedication of commercial-grade Items could endorse:
  - EPRI 3002002982, “Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications”

Regulatory Guidance

Regulatory Guidance development underway…

- DG-1305, "Design and Analysis Computer program Commercial-Grade Dedication Requirements" would address:
  - EPRI Technical Report 1025243, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications"

10 CFR Part 21 Purpose

Part 21:

- Implements Section 206 of the Energy Reorganization Act, 1974
- Requires those entities subject to Part 21 to notify the Commission of when they obtain information indicating that a facility, activity, or basic component:
  - fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order or license of the Commission relating to a substantial safety hazard
  - contains defects that could create substantial safety hazards

Rulemaking - Proposed Areas of Focus

EVALUATION AND REPORTING	Proposed Rule Change	NRC Guidance	Industry Guidance
1. Lack of Regulatory Guidance		x	x
2. Quality Requirements in Procurement Documents		x	x
3. Lack of Clarity in Definition of Basic Component (Part 70)	x		
4. Clarification of Point of Discovery	x		
5. Clarification of Defect	x		
6. Clarification of Delivery	x		
7. Evaluating and Reporting Responsibility		x	x
8. Deferral of Evaluation – 10 CFR 21.21(b)		x	x
9. Use of Licensee Event Reporting (§ 50.72 and § 50.73)	x		
10. Notifications Which Satisfy10 CFR 21.21(d)(2)		x	x
11. Division of Part 21 and § 50.55(e) Requirements	x		
12. Evaluation of Counterfeit, Fraudulent, and Suspect Items		x	x
13. Contemporary Posting Requirements		x	x
14. Training		x	x
15. Lack of Clarity in Eval. and Reporting Req. (Part 70)		x	x

Rulemaking - Proposed Areas of Focus

COMMERCIAL-GRADE DEDICATION	Proposed Rule Change	NRC Guidance	Industry Guidance
A. Lack of Regulatory Guidance		x	x
B. Proper Place for Commercial Grade Dedication Req.	x		
C. Definition of Dedication	x		
D. Definition of Dedicating Entity	x		
E. Definition of Commercial-Grade Item	x		
F. Clarification of 'Basic Component' as Equivalent to 'Safety-Related for Appendix B Facilities		x	
G. Clarification of QA Req. for the Conduct of Dedication for Appendix B Facilities			
H. Sampling Requirements		x	x
I. Software Dedication		x	x

Draft Regulatory Basis Layout

ADAMS Accession No. ML14135A207

- CHAPTER 1 - INTRODUCTION
- CHAPTER 2 – EVALUATING AND REPORTING
- CHAPTER 3 – COMMERCIAL GRADE DEDICTION
- CHAPTER 4 – ADMINISTRATIVE CHANGES
- CHAPTER 5 – BACKFITTING
- CHAPTER 6 – SCHEDULE
- APPENDIX A – PRELIMINARY DRAFT RULE LANGUAGE
- APPENDIX B – DRAFT RULE LANGUAGE (REDLINE/STRIKEOUT)

Draft Regulatory Basis Layout

- **Format of Regulatory Basis**
  - Existing Regulatory Framework
  - Regulatory Issue
  - Proposed Change to Regulations
  - NRC Guidance Development
  - Voluntary Industry Initiatives

Draft Regulatory Basis

QUESTIONS

Draft Regulatory Basis

CHAPTER 2
EVALUATING AND REPORTING

Draft Regulatory Basis

Section 4
Clarification of Discovery

Clarification of Discovery

Existing Regulatory Framework

- 10 CFR 21.3, "Definitions" defines Discovery
- Discovery means:

  "the completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard…"

- 10 CFR 21.21(a) requires that entities subject to Part 21:

  "evaluate deviations and failures to comply to identify defects and failures to comply… as soon as practicable, and… *in all cases within 60 days of discovery*…"

Clarification of Discovery

Regulatory Issue

- The **"completion"** of the documentation first identifying the existence of a deviation or failure to comply is not defined
- Licensees and vendors interpret & implement "discovery" differently
- NRC has noted inadequacies in the timing between the….

#1) point at which licensee or vendor possess sufficient information to determine that a deviation exists and

#2) documented discovery date

Clarification of Discovery

Regulatory Issue (cont.)

Discovery **DOES NOT** occur until a Part 21 (§21.21(a)) eval. begins → **FALSE**

Discovery **OCCURS** when there is enough information to determine a deviation exists → **TRUE**

Clarification of Discovery

Regulatory Issue (cont.)

"Potentially associated with substantial safety hazard" **ONLY** applies when a "deviation or failure to comply" has been determined → **FALSE**

ANY basic component could be associated with a substantial safety hazard → **TRUE**

Clarification of Discovery

Proposed Changes to the Regulations

- **Revise the definition of 'Discovery'**
  - Discovery = first documentation of deviation in a formal process (i.e CR, CAR)
  - When it is determined that, "*based upon the evidence collected,"* a deviation in a basic component exists, the deviation should be documented
  - Documentation date becomes date of discovery
- When a potential deviation is identified, the licensee or vendor should take action without delay to confirm if a deviation exists

Draft Regulatory Basis

QUESTIONS

Draft Regulatory Basis

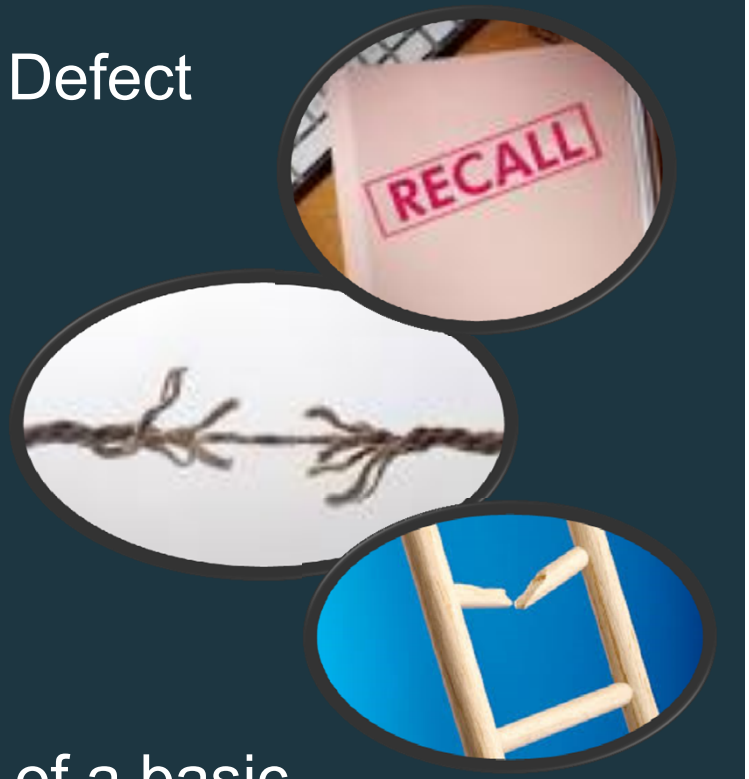
Section 5

Clarification of Defect

Clarification of Defect

Existing Regulatory Framework

- 10 CFR 21.3, "Definitions" defines Defect
- Five (5) definitions
- Defect means:
  - (1) a deviation in a basic component or activity that could create a substantial safety hazard (SSH)
  - (2) installation, use, or operation of a basic component containing a defect



Clarification of Defect

Existing Regulatory Framework

- Defect means (cont.):

(3) a deviation in facility subject to the early site permit, standard design certification, standard design approval, construction permit, combined license or manufacturing license, that could create a SSH

(4) a condition in a basic component that contribute to exceeding of a safety limit

(5) an error in a design certification or standard design approval that could create a SSH

Clarification of Defect

Regulatory Issue

- The definition of defect in 10 CFR 21.3 is complex and difficult to interpret
  - Multiple definitions of "defect," each directed at a specific entity
  - Confusion between entities as to how to apply the definition

Clarification of Defect

Regulatory Issue

- The definition of defect in 10 CFR 21.3 is complex and difficult to interpret (cont.)
  - **FALSE:** Deviations in basic components that have been delivered, but not installed nor used, "cannot" be defects

  - **TRUE:** Deviations identified in basic components that **have been delivered** purchaser but are not installed must be evaluated under 10 CFR 21.21(a)

Clarification of Defect

Regulatory Issue (cont.)

- The definition of defect is complicated by the concept of delivery
  - Some Part 21 evaluations took longer than the 60 days allotted by 10 CFR 21.21(a)
  - Staff efforts to address industry concerns associated with the relationship between defect and delivery were ineffective in clearing up the confusion

Clarification of Defect

Proposed Changes to the Regulations

- Simplify the definition of defect
  - Defect means “a deviation in a basic component delivered to a purchaser that could create a substantial safety hazard”
  - Reduce burden on stakeholders without compromising safety
- A new definition of “delivery” added to regulations

Draft Regulatory Basis

QUESTIONS

Draft Regulatory Basis

Section 6

Clarification of Delivery

Clarification of Delivery

Existing Regulatory Framework

- Concept of delivery is contained in 'defect'
- Defect is defined, in part, as:

  "a deviation in a basic component *'delivered'* to a purchaser for use in a facility or an activity… if, on the basis of an evaluation, the deviation could create a substantial safety hazard"

- 10 CFR 21.21(a) requires that entities "evaluate deviations to identify defects associated with substantial safety hazards as soon as practicable"

Clarification of Delivery

Regulatory Issue

- The concept of delivery is not defined in the regulations
  - Delivery represents the transfer of ownership of between purchaser and supplier, including Part 21 reporting responsibilities
  - Responsibilities associated with the transfer of ownership of basic components have been misinterpreted
  - Entities fail to meet the evaluation and notification requirements in 10 CFR 21.21

Clarification of Delivery

Regulatory Issue (cont.)

- The term "delivered" applies when the basic component has been received and accepted by the purchaser of the component
  - A basic component has been "delivered" when the purchaser has accepted the item through a formal acceptance process (i.e., receipt inspection)
  - After delivery, the ownership of the basic component transfers to the purchaser, including Part 21 evaluation and reporting responsibility
  - Part 21 report needs to be made only after delivery

Clarification of Delivery

Proposed Changes to the Regulations

- Add a definition of "delivery" to Part 21 regulations
  - Delivery means that a purchaser has accepted a basic component through a formal acceptance process (i.e., receipt inspection)
- Clarify evaluation and reporting responsibility between purchaser and supplier
  - When a basic component has been "delivered", the purchaser bears the evaluation and reporting responsibility pursuant to 10 CFR 21.21(a)
- Revise 10 CFR 21.21(a):
  - Evaluation of deviation or failure to comply are ONLY required in those basic components that have been delivered

Draft Regulatory Basis

QUESTIONS

Section 9

Use of Licensee Event Reporting (10 CFR 50.72 and 50.73)

Use of LERs (10 CFR 50.72 and 50.73)

Existing Regulatory Framework

- 10 CFR 21.1 requires any individual director or responsible office to notify the Commission of a defect or failure to comply, "unless he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply"
- 10 CFR 21.2(c) allows a licensee to satisfy Part 21 reporting responsibilities under sections 50.72, 50.72, or 73.71, to avoid duplicate reporting

Use of LERs (10 CFR 50.72 and 50.73)

Existing Regulatory Framework (cont.)

- 10 CFR 21.2(c) states:

  "…evaluation of potential defects and appropriate reporting of defects under §§ 50.72, 50.73, or § 73.71 of this chapter, satisfies… evaluation, notification, and reporting obligation to report defects under this part…"

Use of LERs (10 CFR 50.72 and 50.73)

Regulatory Issue

- Inconsistent approach by licensees on whether only an evaluation or an evaluation and a reporting of a potential defect satisfies Part 21 evaluation and reporting obligations
- The intent of the rule amendment in 1991 was to reduce duplicative reporting, not to relieve the licensee of the obligation to evaluate and report a defect or a failure to comply

Use of LERs (10 CFR 50.72 and 50.73)

Proposed Changes to the Regulations

- Correct the ambiguity by clarifying the statement in 10 CFR 21.2(c):
  - The report of defects under 10 CFR 50.72, 50.73, or 73.71 of this chapter, satisfies each entity's evaluation, notification, and reporting obligation under this part
- No modifications to 10 CFR 50.72 or 50.73 proposed

Draft Regulatory Basis

QUESTIONS

Draft Regulatory Basis

Section 11

Division of Part 21 and

10 CFR 50.55(e) Requirements

Division of Part 21 and 10 CFR 50.55(e)

Existing Regulatory Framework

- Part 21 and 10 CFR 50.55(e) provide nearly identical requirements for reporting of defects and failures to comply
- Both regulations establish requirements for implementing Section 206 of the Energy Reorganization Act of 1974

Division of Part 21 and 10 CFR 50.55(e)

Existing Regulatory Framework (cont.)

- Differences between Part 21 and 10 CFR 50.55(e):
  - 10 CFR 50.55(e) applies to holders of:
    - construction permit
    - combined license, until 10 CFR 52.103(g) finding
    - manufacturing license)
  - 10 CFR 50.55(e) requires reporting of "any significant breakdown in any portion of the quality assurance program"

Division of Part 21and 10 CFR 50.55(e)

Existing Regulatory Framework (cont.)

- Differences between Part 21 and 10 CFR 50.55(e) – cont.:
  - 10 CFR 50.55(e) provides longer record retention requirements for suppliers of basic components:
    - 10 years for notifications to affected licensees or purchasers (vs. 5 years in Part 21)
    - 15 years for records of facilities or purchasers where basic components were delivered (vs. 10 years in Part 21)

Division of Part 21 and 10 CFR 50.55(e)

Regulatory Issue

- Division of nearly identical Part 21 and 10 CFR 50.55(e) requirements has led to misinterpretation
- Regulations are unclear as to when vendors are required to report significant breakdowns in any portion of the QA program that could have produced a defect

Division of Part 21 and 10 CFR 50.55(e)

Proposed Changes to the Regulations

- Remove 10 CFR 50.55(e) and corresponding definitions in 10 CFR 50.2
- Adopt analogous requirements in Part 21
- Delete the requirement to evaluate a significant QA program breakdown

Draft Regulatory Basis

QUESTIONS

Draft Regulatory Basis

Section B

Proper Place for Commercial Grade Dedication (CGD) Requirements

Proper Place for CGD Requirements

Existing Regulatory Framework

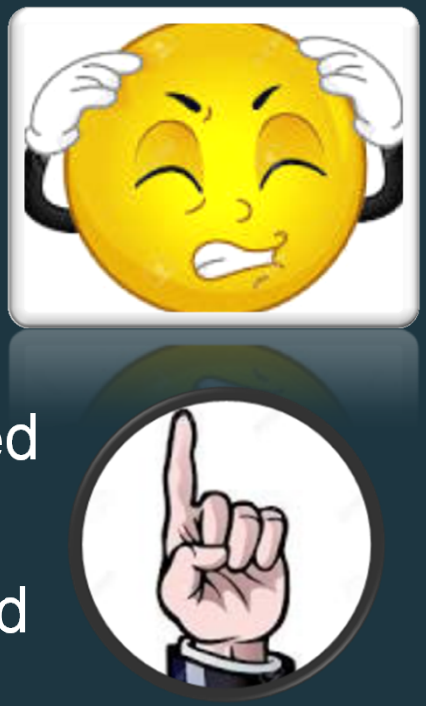
- **1978 amendment to Part 21 (43 FR 48621) provided first definition of CGD:**
  - CG items exempted from Part 21 req. until dedicated for use
  - Framework for dedication largely unchanged since 1978

- **The CGD process is contained in the definition of dedication under 10 CFR 21.3:**
  - "dedication is an acceptance process undertaken to provide reasonable assurance that a CGI…will perform its intended safety function"

Proper Place for CGD Requirements

Regulatory Issue

- Dedication "process" should not reside solely within the definition of dedication
  - Lack of descriptive regulatory requirement
  - Regulation is difficult to apply
  - Basic elements of CGD process (steps and sequence) are not captured
  - Limitations on use of dedication methods are not addressed



Proper Place for CGD Requirements

Regulatory Issue (cont.)

- Licensee and vendors incorrectly implement the dedication process:
  - Failure to define and/or verify critical characteristics
  - Failure to define safety function
  - Failure to document technical evaluation

Proper Place for CGD Requirements

Proposed Changes to the Regulations

- **Restructure Part 21**
  - Separate evaluation & reporting from commercial grade dedication

- **Create 10 CFR 21.71, "Commercial Grade Dedication Requirements"**
  - Define CGD process
  - List basic steps
  - Require documenting technical evaluations
  - Dedication must be conducted in accordance with requirements of Appendix B

Draft Regulatory Basis

QUESTIONS

Draft Regulatory Basis

Section C

Definition of Dedication

Definition of Dedication

Existing Regulatory Framework

- Dedication is defined in 10 CFR 21.3 as:
  - An acceptance process undertaken to provide *reasonable assurance* that CGI to be used as a basic component will perform its intended safety function

Definition of Dedication

Existing Regulatory Framework (cont.)

- **Definition currently describes "how" dedication should be conducted, i.e.:**
  - Identifying critical characteristics
  - Verifying acceptability (by purchaser or third party)
  - In accordance with Appendix B to 10 CFR 50

Definition of Dedication

Regulatory Issue

- **Definition of dedication is complex**
  - Lack of simplicity detracts from basic concept of dedication
  - Current definition contains CGD implementing details
  - Definitions are not the proper place for substantive regulatory requirements (i.e. defining a process)
- **Industry lack understanding of dedication process**
- **Definition is inadequate for dedication of complex items**

Definition of Dedication

Proposed Changes to the Regulations

- **Simplify definition of dedication in 10 CFR 21.3**
  - Remove text referencing “how” dedication should be conducted (i.e. new section 10 CFR 21.71)
  - Definition will be common to power reactors, non-power reactors, and nonreactors

Draft Regulatory Basis

QUESTIONS

Draft Regulatory Basis

Section D

Definition of Dedicating Entity

Definition of Dedicating Entity

Existing Regulatory Framework

- **Dedicating entity is defined in 10 CFR 21.3 as:**
  - The organization performing the dedication process
- **Dedicating entity responsible for**
  - Identifying and evaluating deviations
  - Reporting defects and failures to comply
  - Maintaining records

Definition of Dedicating Entity

Regulatory Issue

- Dedicating entity is only defined for Part 50 plants
- Definition does not apply to Part 52 licensees
  - 2007 Part 21 amendment unintentionally omitted Part 52 entities

Definition of Dedicating Entity

Regulatory Issue (cont)

- **Definition does not apply to Part 70 licensees**
  - Part 70 facilities perform dedication activities, however, applicability to nonreactors was not considered (2007 rev.)
  - The NRC has approved exemption requests from fuel cycle applicants and licensee because of inability to design and manufacture some "basic components"

Definition of Dedicating Entity

Proposed Changes to the Regulations

- Revise definition of dedicating entity in 10 CFR 21.3
  - Remove reference to nuclear power plants
  - Definition will now be inclusive of power reactors, non-power reactors, nonreactors

Draft Regulatory Basis

QUESTIONS

Draft Regulatory Basis

Section E

Definition of Commercial Grade Item

Definition of Commercial Grade Item

Existing Regulatory Framework

- For power reactors, CGI is defined in 10 CFR 21.3 as: "…a structure, system, or component… that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified)"

Definition of Commercial Grade Item

Regulatory Issue

- Incorrect interpretation of CGI for power reactor licensees that a specific critical characteristic can only be verified through in-process inspection
  - Inspection is one of verification methods under the dedication process
  - Other means of the dedication can be used

Definition of Commercial Grade Item

Proposed Changes to the Regulations

- Revise definition of CGI to clarify that it is an item that is not a basic component
- The definition of CGI will be made equivalent for reactor and nonreactor facilities.
  - All items not designed and manufactured under an appropriate QA program would be considered CGI
  - Dedication would be prohibited if any critical characteristic cannot be verified as acceptable

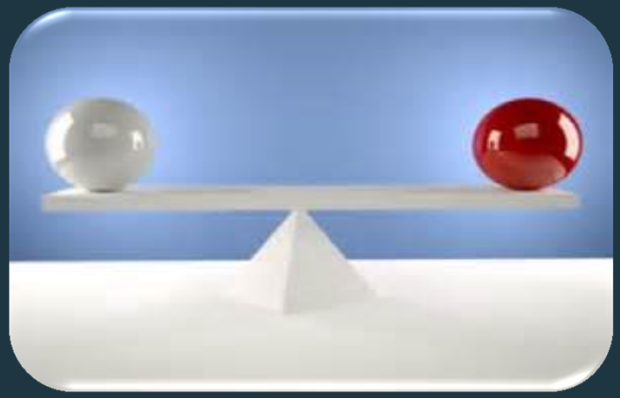
Draft Regulatory Basis

QUESTIONS

Draft Regulatory Basis

Section F

'Basic Component' as Equivalent to 'Safety-Related' For Facilities Subject to Appendix B



‘Basic Component’ as Equivalent to ‘Safety-Related’

Existing Regulatory Framework

- Definitions of basic component and safety-related vary slightly
- Basic component, as it applies to power reactor facilities, is defined in 10 CFR 21.3 as:

  “…a structure, system, or component, or part thereof that affects its safety function necessary to assure:…
  C. The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposure comparable to those referred to in § 50.34(a)(1), § 50.67(b)(2), or § 100.11 of this chapter, as applicable”

'Basic Component' as Equivalent to 'Safety-Related'

Existing Regulatory Framework (cont.)

- Safety-related SSCs for reactor facilities are defined in 10 CFR 50.2 as:
  "Safety-related... means those structures, systems and components that are relied upon to remain functional during and following design basis events to assure…
  (3) The capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposures comparable to the applicable guideline exposures set forth in § 50.34(a)(1) or § 100.11 of this chapter, as applicable"

‘Basic Component’ as Equivalent to ‘Safety-Related’

Regulatory Issue

- Definitions of “basic component” and “safety-related” do not align
- The use of terms “affects its safety function” in the definition of basic component is less specific than that provided in the definition of “safety-related”
  - Inadequate application of QA controls to basic components by vendors and licensees

'Basic Component' as Equivalent to 'Safety-Related'

Proposed Changes to the Regulations

- Revise the definition of basic component to align with safety-related
  - Meaning of basic component is unchanged
- No intention to differentiate between "basic component" and "safety-related" or apply separate criteria to determining which SSCs are basic components or safety-related

Draft Regulatory Basis

QUESTIONS

Draft Regulatory Basis

Section G

QA Requirements for the Conduct of Dedication for Facilities Subject to Appendix B

QA Requirements for Dedication for Facilities subject to Appendix B

Existing Regulatory Framework

- For power reactors, 10 CFR 21.3 includes the following requirement in the definition of dedication:
  "In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR part 50, appendix B"
- No similar statements for QA requirements applicable to dedication activities for other facilities subject to the requirements of Part 21

QA Requirements for Dedication for Facilities subject to Appendix B

Regulatory Issue

- The regulatory framework for dedication, including the application of QA controls, resides primarily in the definition of dedication in 10 CFR 21.3
  - Dedication activities are performed improperly by power reactor licensees, not in accordance with provisions of Appendix B

QA Requirements for Dedication for Facilities subject to Appendix B

Proposed Changes to the Regulations

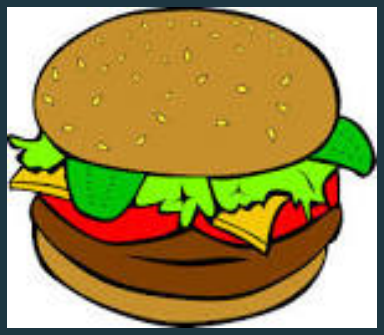
- Add a requirement in the new section on commercial grade dedication (proposed 10 CFR 21.71) that identifies that dedication must be conducted in accordance with Appendix B for the entities subject to requirements of Appendix B

Draft Regulatory Basis

QUESTIONS

Draft Regulatory Basis

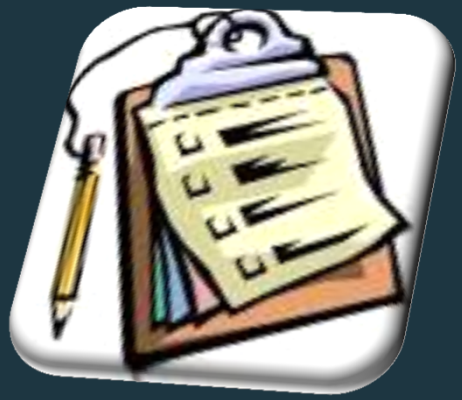
LUNCH BREAK



FUEL CYCLE SESSION
1:00 pm to 4:00 pm

Draft Regulatory Basis

EVALUATING AND REPORTING for Fuel Cycle Facilities



Draft Regulatory Basis

Section 3

Lack of Clarity in the Definition of Basic Component for Nonreactor Facilities and Activities

Clarification of Basic Component

Existing Regulatory Framework

- 10 CFR 21.3, "Definitions" defines Basic Component

  When applied to other facilities and other activities licensed under 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72 of this chapter, basic component means a structure, system, or component, or part thereof, that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard.

Clarification of Basic Component

Regulatory Issue

- Rule lacks clarity and specificity for identification of nonreactor basic components
- Licensees interpret & implement “basic component” differently
- Exemption and license amendment requests have been sought for this term and other Part 21 terminology for fuel cycle facilities

Clarification of Basic Component

Proposed Changes to the Regulations

- Revise definition of "basic component" for fuel cycle facilities
  - Link to terminology used in Subpart H of Part 70
  - Apply regulatory guidance related to substantial safety hazards
    - statement of considerations
    - NUREG-0302
    - NRC guidance related to abnormal occurrences
    - Information Notice 91-39
  - Focus on engineered items to identify scope of "basic component"

Clarification of Basic Component

IROFS A
(engineered)

Capable of independently preventing/mitigating accident

IROFS A is a basic component

IROFS A
(administrative)

IROFS B
(engineered)

Capable of independently preventing/mitigating accident

IROFS B is a basic component

IROFS A
(administrative)

IROFS B
(engineered)

Not capable of independently preventing/mitigating accident

IROFS C
(engineered)

Capable of independently preventing/mitigating accident

IROFS C is a basic component

Clarification of Basic Component

IROFS A
(administrative)

IROFS B
(engineered)

Not capable of independently preventing/mitigating accident

IROFS C
(engineered)

Not capable of independently preventing/mitigating accident

IROFS B and C are basic components

IROFS A
(administrative)

IROFS B
(engineered)

Capable of independently preventing/mitigating accident

IROFS C
(engineered)

Capable of independently preventing/mitigating accident (identical to IROFS B above)

Both IROFS B and C are basic components (lack diversity)

IROFS A
(administrative)

IROFS B
(engineered)

Capable of independently preventing/mitigating accident

IROFS C
(engineered)

Capable of independently preventing/mitigating accident; NOT identical to IROFS B

No IROFS are basic components

Clarification of Basic Component

Proposed Changes to the Regulations

System, structure, or component (SSC) designated as an IROFS

Defect or failure to comply could cause the performance requirements of § 70.61 to be exceeded

Basic Component

Redundant engineered IROFS exist to perform the same safety function

Administrative IROFS exist to perform the same safety function

Diverse engineered IROFS exist to perform the same safety function

Basic Component

Basic Component

NOT a Basic Component

Draft Regulatory Basis

QUESTIONS

Draft Regulatory Basis

Section 15

Lack of Clarity in Evaluating and Reporting Requirements for Part 70 Licensees

Part 70 Evaluating and Reporting

Existing Regulatory Framework

- 10 CFR 21.21 describes the evaluating and reporting requirements for entities subject to Part 21:

  Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to -- (1) Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (a)(2) of this section, in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected.

Part 70 Evaluating and Reporting

Existing Regulatory Framework

- Promulgation of Subpart H to 10 CFR Part 70
  - Risk-informed and performance-based
  - Integrated Safety Analysis performed to determine need for items relied on for safety to limit the risk from credible accident sequences
  - Items relied on for safety may be engineered or administrative
    - High degree of flexibility in selection of controls

Part 70 Evaluating and Reporting

Regulatory Issue

- Lack of clarity as to whether implementation of Part 21.21 enables consideration of risk-informed and performance-based approaches
- Very limited guidance available for evaluating and reporting
- Consideration should be given to aligning Part 70 and Part 21 to ensure regulatory clarity and stability

Part 70 Evaluating and Reporting

Proposed Guidance

- Describe when an evaluation is required
- Describe the use of administrative controls in the evaluation and reporting process

Part 70 Evaluating and Reporting

Proposed Guidance

Deviation in an IROFS that is a basic component

Evaluation:

Administrative IROFS available that would have prevented performance requirements from being exceeded

Not a defect.
No report required.
Retain documented evaluation.

Evaluation:

Administrative IROFS either not designated or not available to prevent performance requirements from being exceeded

Defect.
Report under Part 21.
Retain documented evaluation.

Draft Regulatory Basis

Draft Regulatory Basis

COMMERCIAL GRADE DEDICATION for Fuel Cycle Facilities

Draft Regulatory Basis

Section A

Lack of Regulatory Guidance

Lack of Guidance for Fuel Facility Dedication

Existing Regulatory Framework

- Dedication is described in 10 CFR 21.3, for facilities other than nuclear power plants as follows:

  dedication occurs after receipt when that item is designated for use as a basic component

Lack of Guidance for Fuel Facility Dedication

Regulatory Problem

- Lack of guidance for commercial grade dedication as it applies to fuel cycle facilities
- Requirements for Management Measures implemented via Subpart H of 10 CFR Part 70 to ensure the availability and reliability of IROFS
  - Current industry guidance (i.e., EPRI NP-5652) not readily applied to most fuel cycle facilities

Lack of Guidance for Fuel Facility Dedication

Proposed Guidance

- Licensees that are subject to Subpart H of Part 70 and not subject to Appendix B to 10 CFR Part 50 may satisfy the requirements of commercial grade dedication by implementing existing management measures programs under Part 70
- The application of management measures programs ensures the availability and reliability of IROFS at fuel cycle facilities
  - Management measures reviewed and approved by NRC as part of the licensing process and subject to periodic inspections to assess licensee compliance with license commitments

Draft Regulatory Basis

Section B

Proper Place for Dedication Requirements

Dedication Requirements

Existing Regulatory Framework

- Dedication is described in 10 CFR 21.3, for facilities other than nuclear power plants as follows:

  dedication occurs after receipt when that item is designated for use as a basic component

Dedication Requirements

Regulatory Problem

- Regulatory framework for dedication is contained in definitions
- Definition is not sufficiently robust to communicate essential requirements for dedication process

Dedication Requirements

Proposed Change to the Regulations

- For fuel cycle facilities that are subject to the requirements of Subpart H but not subject to Appendix B as part of their licensing basis, no change to the requirements are proposed.
  - Guidance discussed in Section A of draft regulatory basis will be applied to communicate link between management measures programs and satisfactory performance of dedication
- For fuel cycle facilities that are subject to the requirements of Subpart H and Appendix B as part of their licensing basis, newly developed Section 21.71 would apply.

Draft Regulatory Basis

Section E

Definition of Commercial Grade Item

Definition of Commercial Grade Item

Existing Regulatory Framework

- Commercial grade item is defined in 10 CFR 21.3, for facilities other than nuclear power plants as an item that is:

  (i) Not subject to design or specification requirements that are unique to those facilities or activities;

  (ii) Used in applications other than those facilities or activities; and

  (iii) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog)

Definition of Commercial Grade Item

Regulatory Problem

- Definition restricts the use of commercial grade items to items that are generic in nature
  - Result is that dedication cannot be used to obtain a basic component that is unique to its application
- Restrictiveness has caused the need for licensing and exemption requests to enable dedication of commercial items needed for fuel facility design, construction, and operation

Definition of Commercial Grade Item

Proposed Change to the Regulations

- Revise the definition of commercial grade item to clarify that it is simply an item that is not a basic component

Draft Regulatory Basis

Section G

Clarification of Quality Assurance Requirements for the Conduct of Dedication for Facilities Subject to Appendix B

Link Between Dedication and QA Requirements

Existing Regulatory Framework

- 10 CFR 21.3 includes in the definition for dedication as applied to power reactor licensees the requirement that:
  - In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR part 50, appendix B.
- There are no similar statements to identify the QA requirements applicable to dedication activities for other facilities subject to the requirements of Part 21.

Link Between Dedication and QA Requirements

Regulatory Problem

- Lack of description within Part 21 and guidance associated with Part 21 to describe QA controls that should be applied to dedication activities for fuel facilities

Link Between Dedication and QA Requirements

Proposed Changes

- For fuel cycle facilities regulated under Subpart H and not subject to the requirements of Appendix B to 10 CFR Part 50:
  - No rule change proposed; guidance discussed previously will describe link between management measures program and dedication
- For fuel cycle facilities regulated under Subpart H and subject to the requirements of Appendix B to 10 CFR Part 50 (e.g., facilities that process plutonium):
  - Proposed rule changes will clarify the applicability of Appendix B QA controls to dedication activities

Draft Regulatory Basis

QUESTIONS

CHAPTER 4
ADMINISTRATIVE CHANGES

i. Addition of Reference to 10 CFR Part 76

- Definition of substantial safety hazard in 10 CFR 21.3 omits facilities regulated under 10 CFR Part 76, "Certification of Gaseous Diffusion Plants"
- Add a reference to Part 76 facilities to the definition of substantial safety hazard

ii. Incorrect Numbering in 10 CFR 50.55(e)(4)

- 10 CFR 50.55(e)(4), previously stated: "Notification. (i) The holder of a facility construction permit subject to this part, combined license… and manufacturing license… must notify the Commission… as discussed in paragraph (e)(10) of this section"
- The reference to paragraph (e)(10) was in error
- The error was corrected to reference paragraph (e)(4)(v)
  - Federal Register, Vol. 78, June 7, 2013, p. 34248

Draft Regulatory Basis

QUESTIONS

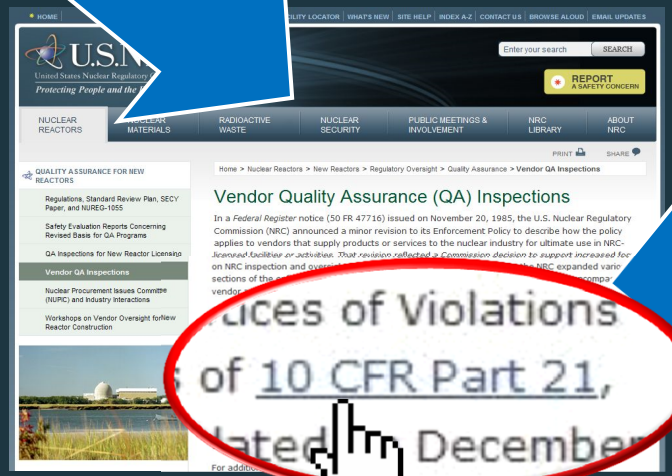
OPEN DISCUSSION

How to Get Involved

Search for NRO Docket **NRC-2012-0012**

How to Get Involved (cont'd)

Jermaine Heath
Office of New Reactors
Jermaine.Heath@nrc.gov
(301)415-6066



MEETING ADJOURN